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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/299,139 | 04/23/1999 | JEFFREY BROWNING | A013 | 2882 |

7590 03/15/2006
AMY E. MANDRAGOURAS
LAHIVE & COCKFIELD, LLP
28 STATE STREET
BOSTON, MA 02109

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1643

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/299,139 | BROWNING ET AL. | |
| | Examiner | Art Unit | |
| | Christopher H. Yaen | 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/15/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 51,53,55,56,71,72,75,77,78,84,86,88,89,95-98,100,102-104,106,108-112,114 and 116-121.

Continuation of Disposition of Claims: Claims rejected are 51,53,55,56,71,72,75,77,78,84,86,88,89,95-98,100,102-104,106,108-112,114 and 116-121.

DETAILED ACTION

Re: Browning et al

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/1/2005 has been entered.
2. The amendment filed 12/1/2005 is acknowledged and entered into the record. Accordingly, claims 1-50, 52,57-70, 73-74, 76,79-83,85,87,90-94,99,101,105,107, 113, and 115 are canceled without prejudice or disclaimer.
3. Claims 51,53,55-56,71-72,75,77-78,84,86,88-89,95-98,100,102-104,106,108-112,114, and 116-121 are pending and examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

5. The Information Disclosure Statement filed 12/15/2005 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Specification

6. The disclosure is objected to because of the following informalities:

Art Unit: 1643

a. The specification contains sequences which have not been associated with a specific sequence identifier or SEQ ID No. 37 CFR 1.82(d) requires the use of the assigned sequence identifier (SEQ ID No:) in all instances where the description of a patent application refers to a sequence and whenever a sequence or fragment thereof is claimed (see MPEP 2422.03). Specifically, the specification on page 59, for examples, recites two primers that have not sequence identifiers. Appropriate correction is required

Appropriate correction is required.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

7. The rejection of claims 53,75,86,100,106, and 114 under 35 USC § 112, 1st paragraph is maintained for the reasons of record. Applicant arguments are direct to the recitation of the term “soluble” LT-β R, however, the final rejection indicated that the recitation of the term “functional” fragments is not supported by an adequate written description in the specification as filed. Applicant indicates that the specification has characterized the soluble portions of the LT-β R and indicates that the term is art recognized. To support such assertions, applicant cites Force *et al*. Applicant’s arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The instant claims do not provide sufficient structural and functional characteristics coupled with a known or disclosed correlation between function and structure. Since the disclosure fails to describe the common attributes or characteristics

Art Unit: 1643

that identify members of the genus of "functional fragments" of SEQ ID No: 1. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3). In the instant case, applicant have provided sufficient written description for LT-b R of SEQ ID No: 1, or the soluble receptor binding domain of LT-b R, however, applicant has not provided any identifying structural characteristics coupled with a known or disclosed correlation between structure and function to be entitled to the broad genus of "functional fragments" as claimed. Moreover, applicant has not provided a representative number of species to be entitled to a genus of fragments claimed to show possession of the genus at the time of the invention. In the absence of structural characteristics that are shared by members of the genus, the skilled artisan would conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. "Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." *Id.* at 1566, 43 USPQ2d at 1404 (quoting *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606). Also see *Enzo-Biochem v. Gen-Probe* 01-1230 (CAFC 2002).

NEW REJECTIONS

Claim Rejections - 35 USC § 112, 2nd paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 51,53,55-56,71-72,75,77-78,84,86,88-89,95-98,100,102-104,106,108-112,114, and 116-121 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. In particular, all claims are deemed indefinite because it is unclear as to whether applicant intends for the LT ligand to be fused to the heterologous protein domain or whether the LT- β R is to be fused to the heterologous domain.
- b. With regard to claim 51, the claim recites the limitation "the mammal" in line 2. There is insufficient antecedent basis for this limitation in the claim,

because there is no previous recitation of any mammal. Applicant may overcome this rejection by amending the claim to "the human".

Claim Rejections - 35 USC § 112, 1st paragraph

10. Claims 51,53,55-56,71-72,75,77-78,84,86,88-89,95-98,100,102-104,106,108-112,114, and 116-121 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

The claims recite the administration of a LT- β R, which comprises at least one ligand binding domain that selectively binds to a surface LT ligand fused to one or more heterologous protein domains. The specification as filed does not support a fusion protein comprising a surface LT ligand conjugated or fused to a heterologous protein domain as claimed. Applicant may overcome this rejection by indicating that the LT- β R is fused to the heterologous domain.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

Art Unit: 1643

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Note: for the purposes of this rejection, the claims are interpreted as being a method of administering a LT- β R fused to a heterologous protein domain, as supported in the specification, see for example page 58, example 1.

12. Claims 51,53,55-56,71-72,75,77-78,95-96,100,102-109, and 119-121 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 55-56,59-62, and 64 of copending Application No. 10/003,211. Although the conflicting claims are not identical, they are not patentably distinct from each other because SLE is an autoimmune disease associated humoral immune responses. Therefore, the claims of the co-pending application are deemed to be a species encompassed within the broad claims of inhibiting a humoral immune response, or treating an antibody-mediated disease as claimed. Moreover, the claims of the instant application represents a genus of immune responses, of which include autoimmune diseases as claimed in co-pending application 10/03,211. As such, a species anticipates a genus.

Art Unit: 1643

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen, Examiner
Art Unit 1643
March 2, 2006


CHRISTOPHER YAEN
PATENT EXAMINER